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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/726,135 | 12/01/2003 | Robert F. Rosenbluth | MCRVT-029G | 3524 |
| <div>7590 02/05/2008</div> <div>Robert D. Buyan STOUT, UXA, BUYAN & MULLINS, LLP Suite #300 4 Venture Irvine, CA 92618</div> | | | | |
| | | | EXAMINER | |
| | | | WOO, JULIAN W | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3773 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/726,135 | Applicant(s) ROSENBLUTH ET AL. | |
| | Examiner Julian W. Woo | Art Unit 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79-106 and 111-128 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 79-106 and 111-128 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 4, 2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 124, 125, and 127 are rejected under 35 U.S.C. 102(e) as being anticipated by Smalling (6,730,119). Smalling discloses, at least in figures 1A and 6A and in col. 14, line 40 to col. 15, line 27; a method of treating an aneurysm of a vessel, where the method includes advancing a distal end of a cannula (410) to an aneurysm, positioning and anchoring an endovascular graft to a wall of the vessel over the aneurysm, capturing the cannula (with a cell in the wall of the graft and with the graft outer covering) between an outside surface of the graft and an inside surface of the

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vessel wall, and delivering an expansile material (310, e.g., coils, foam, and gel), where a catheter (400) is advanced to a position in proximity to the aneurysm.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 79-81, 84, 96, 101, 102, and 118-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wholey et al. (2002/0169497) in view of Abolfathi et al. (5,786,679). Wholey et al. disclose, at least in figures 7 and 24 and in paragraphs [0045] and [0050] to [0052], the invention substantially as claimed. Wholey et al. disclose a method for preventing leakage into a perigraft space (14) between an endovascular graft (e.g., 28) and an adjacent portion of an aneurysmic blood vessel wall, a method of treating a vessel within a body, and a method of treating an aneurysm of a vessel, where the methods include a device or expansile material comprising a solid member (36) having expansile polymeric material (e.g., gel, organic elastomers,

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and polymeric foams) disposed thereon is provided, a flexible cannula (32) or a delivery device is inserted into the lumen of the blood vessel or positioned in proximity of a target location within the vessel; where the graft is expanded at the target location such that a perigraft space is formed, where the device is introduced through the cannula and into a perigraft space between the endovascular graft and the blood vessel wall or the aneurysm. However, Wholey et al. do not disclose disposing the endovascular graft over a distal end of the cannula and over the adjacent portion of the blood vessel wall such that the distal end of the cannula is captured between the external surface of the endovascular graft and a wall of the blood vessel that mates with the external surface of the endovascular graft, pressing the distal end of the delivery device between an external surface of the graft and internal surface of the vessel, or capturing the cannula between an outside surface of the graft and an inside surface of the vessel wall, and Wholey et al. do not disclose that the expansile polymeric material is substantially in a non-expanded state when it is introduced into the perigraft space through the cannula and allowed to expand to an expanded state in the perigraft space. Wholey et al. also do not disclose that the total volume of non-expanded expansile polymeric material is predetermined before its expansion in the perigraft space. Wholey et al. do not disclose that the expansile material is a hydrogel or is on a coil. Abolfathi et al. teach, in figures 4 and 7 and in col. 5, line 56 to col. 6, line 18; col. 7, lines 16-39; and col. 8, line 56 to col. 9, line 12; disposing an expandable endovascular device (20) or graft (90) over the distal end of a cannula (65) or delivery device and over an adjacent portion of a blood vessel wall such that the distal end of the cannula is captured between an external

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surface of the endovascular device or graft and the wall of the blood vessel that mates with the external surface of the endovascular device or graft. Abolfathi et al. also teach an expansile polymeric material (e.g., hydrogel) that is introduced through a cannula in a non-expanded state allowed to expand to an expanded state in an aneurysmic space, and Abolfathi et al. teach coils as an expansile material. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Abolfathi et al., to modify the method of Wholey et al., so that the cannula is captured as claimed, and such that expansile material as claimed is applied. A cannula as applied by Abolfathi et al. would not only be useful for introducing expansile material into an aneurysmic space, it may be used to aspirate part of the volume of the space and thereby reduce the size of the aneurysm from its untreated condition without having to penetrate a graft wall or a blood vessel wall. It also would have been obvious to one having ordinary skill in the art to predetermine the total volume of non-expanded expansile polymeric material to be deployed in the perigraft space. Such a predetermination would allow the selection of an appropriate size for the device, so that it would expand and fill the perigraft space that has been sized. Also, introducing an expansile material through a cannula in an unexpanded state and allowing the material to expand to an expanded state in an aneurysmic space would ease insertion of the material through a small-diameter cannula and allow controlled placement of the material within the space. Also, it would be obvious to one having ordinary skill in the art, in view of Abolfathi, to apply hydrogel or coils in the method of Wholey et al. A hydrogel can harden and/or swell in order to close off an aneurysmic cavity, while coils

can induce thrombosis of blood within the cavity. Wholey et al. in view of Abolfathi et al. also do not disclose that the polymeric material expands to its expanded state in an environment having a pH of about 7.4 or as the pH of the environment increases. (Abolfathi et al. teach hardening of a hydrogel or polymer according to pH; i.e., the hydrogel is pH-sensitive). Nevertheless, it would have been obvious to one having ordinary skill to apply a material so that it expands at a pH of about 7.4 or as the pH of the environment increases, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

6. Claims 82, 83, 85-95, 100, 103-106, 112, and 114-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wholey et al. (2002/0169497) in view of Abolfathi et al. (5,786,679), and further in view of Greene, Jr. et al. (6,238,403). Wholey et al. in view of Abolfathi et al. disclose the invention substantially as claimed, but the combination does not disclose that the expansile polymeric material is radiopaque or radiopaque by the incorporation of radiopaque monomers. Greene, Jr. et al. teach, in col. 6, lines 14-25, an expansile polymeric material that is radiopaque or radiopaque by the incorporation of radiopaque monomers. Thus, it would have been obvious to modify the expansile polymeric material of the device of Wholey et al. in view of Abolfathi et al., so that is radiopaque. Radiopacity would allow visualization of the device by conventional imaging techniques. Wholey et al. in view of Abolfathi et al. do not disclose that the device is initially attached to a delivery member by way of a detachable connection. Greene, Jr. et al. teach, in col. 7, lines 19-34; a device that is initially

attached to a delivery member (30) by way of detachable connection (24). It would have been obvious to one having ordinary skill to modify the device of Wholey et al. in view of Abolfathi et al., so that it has the characteristics as taught by the device (10) of Greene, Jr. et al. Such a device and a delivery member would ease deployment of the device into the perigraft space and allow rapid separation of the device from the delivery member and the cannula. Wholey et al. in view of Abolfathi et al. also do not disclose that the solid member is an elongate, filamentous, or wire member; that the polymeric material is in the form of pellets spaced apart by coil spacers comprising the solid member, and that the solid member is formed of platinum, platinum and tungsten, polymeric material, or PVA. Greene, Jr. et al. teach, in col. 5, lines 12-46, a solid member and spacers (14, 16) and polymeric material (12) as claimed above. It would have obvious to one having ordinary skill in the art to modify the solid member and polymeric material of the device of Wholey et al. in view of Abolfathi et al. to the characteristics as claimed and as taught by Greene, Jr. et al. Such a solid member and a porous, hydrophilic, polymeric material would produce a highly flexible, biocompatible, and visible device that can easily be deployed through a cannula to an aneurysmic site, where the device would effectively embolize. Wholey et al. in view of Abolfathi et al. and/or Greene, Jr. et al. do not disclose/teach the pore size or porosity of the polymeric material as claimed. Nevertheless, it has been held that discovering an optimum value of a result effective variable (pore size or porosity) involves only routine skill in the art. Wholey et al. in view of Abolfathi et al. and/or Greene, Jr. et al. do not disclose that the cannula comprises a plastic tube. Nevertheless, it has been held to be within the

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general skill of a worker in the art to select a known material on the basis for its suitability for its intended use as a matter of design choice. Wholey et al. in view of Abolfathi et al. and/or Greene, Jr. et al. do not disclose performing the method after detection of an endoleak. Nevertheless, it would have been obvious to one having ordinary skill in the art to perform the method after detection of the endoleak in order to pinpoint the leak, embolize the located site, and prevent future leakage.

7. Claims 79, 96-99, and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smalling (6,730,119) in view of in view of Abolfathi et al. (5,785,679). Smalling discloses, at least in figures 1A and 6A and in col. 14, line 40 to col. 15, line 27; the invention substantially as claimed. Smalling discloses a method for preventing leakage into a perigraft space (305) between an endovascular graft (1100) and an adjacent portion of an aneurysmic blood vessel wall and a method of treating a vessel within a body, where the methods include a device or expansile material comprising a solid member (310) having expansile polymeric material (e.g., coils, foam, and gel) disposed thereon is provided, where the a cannula (410) or delivery device is inserted into the lumen of the blood vessel or positioned in proximity of a target location within the vessel, where the device or expansile material is introduced through the cannula or delivery device and through a catheter or microcatheter (400), and into the perigraft space; where the cannula is also advanced through a hollow needle (192) in tissue of a patient's body. However, Smalling does not disclose disposing the endovascular graft over a distal end of the cannula and over the adjacent portion of the blood vessel wall

such that the distal end of the cannula is captured between the external surface of the endovascular graft and a wall of the blood vessel that mates with the external surface of the endovascular graft, and Smalling does not disclose that the expansile polymeric material is substantially in a non-expanded state when it is introduced into the perigraft space through the cannula and allowed to expand to an expanded state in the perigraft space. Abolfathi et al. teach, in figures 4 and 7 and in col. 5, line 56 to col. 6, line 18; col. 7, lines 16-39; and col. 8, line 56 to col. 9, line 12; disposing an endovascular device (20) or graft (90) over the distal end of a cannula (65) or delivery device and over an adjacent portion of a blood vessel wall such that the distal end of the cannula is captured between an external surface of the endovascular device or graft and the wall of the blood vessel that mates with the external surface of the endovascular device or graft. Abolfathi et al. also teach an expansile polymeric material (e.g., hydrogel) that is introduced through a cannula in a non-expanded state allowed to expand to an expanded state in an aneurysmic space. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Abolfathi et al., to modify the method of Smalling; so that the cannula is captured as claimed, and such that expansile material as claimed is applied. A cannula as applied by Abolfathi et al. would not only be useful for introducing expansile material into an aneurysmic space, it may be used to aspirate part of the volume of the space and thereby reduce the size of the aneurysm from its untreated condition without having to penetrate a graft wall or a blood vessel wall. Also, introducing an expansile material through a cannula in an unexpanded state and allowing the material to expand to an expanded state in an

aneurysmic space would ease insertion of the material through a small-diameter cannula and allow controlled placement of the material within the space. Smalley also does not disclose that the microcatheter has a lumen of .005-.050 inch in diameter. Nevertheless, it would have been a matter of obvious design choice to one having ordinary skill in the art at the time the invention was made to size the lumen as claimed, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

8. Claims 111 and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wholey et al. in view of Abolfathi et al. as applied to claim 79 above, and further in view of Goupil et al. (6,676,971). Wholey et al. in view of Abolfathi et al. disclose the invention substantially as claimed, but do not disclose that the cannula is rigid or comprises a metal tube. Goupil et al. teach, in col. 18, lines 41-63, accessing a perigraft space with a cannula (a catheter or a syringe) for delivery of an embolic device, where the distal end of the cannula may be advanced through a patient's body (e.g., a patient's back) and through the wall of the blood vessel adjacent to the graft and into the perigraft space. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Wholey et al. in view of Abolfathi et al. such that a substantially rigid cannula or a cannula formed of a metal tube is applied, since such a cannula would allow penetration of tissue for access to the perigraft space. Moreover, it is held to be within the general skill of a worker in the art to

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select a known material (e.g., a rigid or metal material) on the basis of its suitability for the intended use as a matter of obvious design choice.

Response to Amendment

9. Applicant's arguments with respect to claims 79-106 and 111-128 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

February 4, 2008